NASA Procedural Requirements

NPR 7100.1
Effective Date: March 28, 2003
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COMPLIANCE IS MANDATORY

Printable Format (PDF)

Subject: Protection of Human Research Subjects

Responsible Office: Office of the Chief Health & Medical Officer

APPENDIX A: Definitions

1. Assurances are either a Single Project Assurance (SPA) or Multiple Project Assurance (MPA) which is a formal, written statement in which an institution promises to comply with applicable rules governing research with human subjects. An SPA or MPA must be provided by the IRB prior and accepted by the appropriate Federal agency prior to commencing of any NASA research involving human subjects. An SPA or MPA must cover all research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

2. Authorized NASA Official (ANO) is the official designated by the NASA Administrator who is empowered, subject to conditions and limitations imposed by an immediate supervisor, to authorize research involving human subjects. This has been designated in NPD 7100.8D as the Chief Health and Medical Officer (CHMO).

3. Conducted Research is research involving a PI or subordinate researcher who is a NASA employee.

4. Crewmember is an astronaut, payload specialist, or aviation personnel assigned to a spacecraft or an aircraft mission who may volunteer as a research subject and/or participate as a research technician for a research experiment as part of their employment.

5. Funded Research is research that is partially or completely underwritten by NASA through a contract, cooperative agreement, grant, or other funding mechanism, and which does not also involve permission by NASA to utilize NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles.

6. Human Subject is a living person who is an integral part of a test, or other substantive evaluative procedure and about whom the PI (whether professional or student) obtains (1) research data through intervention or interaction; or (2) identifiable private information.

7. Informed Consent consists of oral or written acknowledgement by a research subject that he/she understands the nature of the research to be performed and his/her obligations in participating in the research, the potential risks to health and well-being by participating as a research subject, and other tests or therapies available if the subject is a medical patient seeking health care; that he/she has been allowed to ask questions relating to the research to be performed; and is allowed to quit the research activity at any time (except if it would cause greater harm to the subject). The elements of informed consent are full disclosure, adequate comprehension, and voluntary choice to and for the research subject.

8. An Institutional Review Board (IRB) is a committee approved by NASA and established in accordance with this NPG or approved by the DHHS under a current Multiple Project Assurance (MPA) to review research involving human subjects and their activities for the adequacy of procedures that protect human subjects in research.

9. Interaction includes communication or interpersonal contact between the investigator and the subject.

10. Intervention includes both physical testing procedures by which data are collected (for example, equipment used on a person) and manipulation of the subject or the subject's environment for research purposes.

11. Life Sciences Research includes biomedical, biological, human factors, psychological, environmental health, and life-support experimentation.

12. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Persons employed in hazardous occupations are not expected to submit to greater risks than persons employed in non-hazardous occupations. Examples of minimal risk activities are presented in Appendix B.

13. Principal Investigator is the researcher who has overall responsibility for all aspects of the funded and/or sponsored research project.

14. Private information includes information provided for specific purposes about a subject's medical, physiological, or behavioral status or history about which the individual can reasonably expect that no observation or recording is taking place and which the individual can reasonably expect shall not be made public.

15. Research is a systematic investigation, including development, testing, and evaluation, which may be designed to test a hypothesis, enable conclusions to be drawn and, thereby, develop or contribute to knowledge in general. The research is described in a formal protocol that sets forth an objective and a set of procedures designed to reach the stated objective.

16. Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

17. Serious Harm is a temporary or permanent illness, injury, disability, or death.

18. Sponsored Research is investigative and commercial experimental work approved by NASA to permit the utilization of NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles, whether or not NASA funds are used to support the research.

19. Supported Research is NASA-funded or -sponsored research.

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